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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,918	11/24/2003	Amon Nagler	85189-5500	9844
28765	7590	07/14/2005	EXAMINER	
WINSTON & STRAWN LLP 1700 K STREET, N.W. WASHINGTON, DC 20006			HENLEY III, RAYMOND J	
			ART UNIT	PAPER NUMBER
			1614	

DATE MAILED: 07/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

10/723,918

Applicant(s)

NAGLER ET AL.

Examiner

Raymond J. Henley III

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 June 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☐ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 28 June 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☒ Applicant's reply has overcome the following rejection(s): the objection to claims 9 and 15.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 9-11 and 15-17.

Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

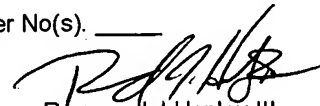
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attachment.

12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). _____

13. ☒ Other: See Continuation Sheet.


Raymond J. Henley III
Primary Examiner
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Continuation of 13. Other: "said medicament" in claim 17 has no antecedent basis and is objectionable.

Attachment to Advisory Action

Applicants' Amendment After Final filed January 28, 2005 has been received and entered into the application. Accordingly, claims 9 and 15 have been amended. In view thereof, the objections to claims 9 and 15 as set forth in the previous Office action dated January 28, 2005 are withdrawn.

It is newly noted that in claim 17, the term "said medicament" does not have antecedent basis. This is an objectionable matter and not a matter for appeal.

Claim Rejection - 35 USC § 103

Claims 9-11 and 15-17 would remain rejected under 35 U.S.C. 103(a) as being unpatentable over Pines et al. (U.S. Patent No. 5,449,678), already of record, for the reasons maintained in the Final Office action dated January 28, 2005.

Applicants' arguments presented in the After-Final response have been considered, but fail to persuade the Examiner of error in his determination because such fail to patentably distinguish the present subject matter from that of the prior art.

In particular, Applicants have argued that the mechanism of action proposed in Pines, i.e., decreasing collagen type I synthesis, may not be the only mechanism involved (see Applicants' amendment at page 6, "halofuginone may act by inhibiting collagen type I synthesis, but other as yet to be determined mechanisms may also be involved..."). This does not distinguish over Pines because regardless of how the active agent of Pines functions, Pines nevertheless teaches the treatment of fibrotic conditions which is ultimately germane to the instant issue of obviousness.

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Applicants have also argued that their invention is distinguished from Pines because in applicants' specification, the alleged difficulties of predicting the *in vivo* effects of Halofuginone based on results of *in vitro* experiments are disclosed. However, to the Examiner, absolute predictability is not required for a finding of obviousness. "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976)." (see MPEP § 2143.03). Pines clearly discloses that Halofuginone may be used for fibrotic disorders throughout cols. 3-7 and such is sufficient to enable one skilled in the art to make and use the invention of Pines. Here, applicant have not provided facts effectively rebutting this position. Rather, Applicants have argued that based on the data shown by Pines in avian skin fibroblasts and chondrocytes, one skilled in the art would not have had a reasonable expectation of using Halofuginone in humans to attenuate renal fibrosis (see the amendment at page 7). In response, it should first be noted that data is not required for a reference to be enabling. Also, while Pines shows certain data and one may or may not be able to draw certain conclusions therefrom is not impressive. Pines clearly teaches that Halofuginone can be used "regardless of tissue or animal species" (col. 3, line 67). This teaching need not be supported by data. It is taken as accurate. Applicants have not effectively refuted the teachings of the patentee.

Finally, Applicants have argued that Pines takes a "general approach" which amounts only to an "obvious to try" situation (see the amendment at page 7). In response, it is believed that the claimed subject matter would have been "obvious to do" in light of the clear, accurate teachings in Pines to use the claimed specified active agents for fibrotic conditions. Applicants

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have not shown that the treatment of renal fibrosis provides for any results that would not have been expected from the teaching of Pines.

Accordingly, the claims remain properly rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Raymond J Henley III
Primary Examiner
Art Unit 1614

July 8, 2005